K072049
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510(K) SUMMARY (per 21 CFR 807.92)

Name of Submitter:	BMEYE B.V. Academic Medical Center, Suite K2-245 Meiberg Dreef 9. 1105 AZ Amsterdam, The Netherlands
Contact Person:	Jacqueline Emery, BSEE CliniQuest, Inc., 74 Pleasant St., Westford, MA 01886, USA Tel: 978-692-0630/ Fax: 978-692-2609/ jacqueline.emery@cliniquest.net
Date Prepared:	June 25, 2007
Trade Names:	NEXFIN_HD™ Continuous Non-Invasive Hemodynamic Monitor
Classification	Class II
Classification Name	– CFR 870.1130, System, measurement, blood pressure, non-invasive, DXN – CFR 870.2770, Plethysmograph, impedance, DSB
Predicate:	The NEXFIN_HD is substantially equivalent to the Finometer (K023723).
Device description	The BMEYE NEXFIN_HD cardiovascular monitor is a *non-invasive* monitor that enables the *continuous* assessment of a patient's cardiovascular function based on the scientific method of Peňáz - Wesseling. The NEXFIN_HD measures continuous non-invasive blood pressure (Systolic, Diastolic and Mean) and heart rate as well as a Cardiac Output (CO), which is derived, non-invasively, from the blood pressure waveform. The monitor also calculates derived hemodynamic parameters.
Intended Use:	The BMEYE NEXFIN_HD is intended to, non-invasively and continuously, measure blood pressure and hemodynamic parameters in adult patients. The NEXFIN_HD monitor should be calibrated with a thermodilution measurement, or other accurate reference determination of cardiac output, to ensure optimal accuracy. The device is intended for use by physicians or other properly trained medical personnel in a hospital or other appropriate clinical setting.
Technology	The device employs the same functional technology as its predicate device.
Functional/ Safety Testing:	The NEXFIN_HD has successfully undergone safety testing as well as functional testing to demonstrating equivalence to its predicate devices. The following quality assurance measures were applied to the device: – Risk Analysis – Requirements Review – Design reviews – Code Inspections – Verification and Validation – Bench Testing (for Cardiac Output functionality) – Clinical Testing (for NBP functionality) – Biocompatibility Testing – Safety Testing
Conclusion:	The results of this testing demonstrates that the device is safe and effective and substantially equivalent to its predicate device.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 9 2007

BMEYE B. V.
c/o Ms. Jacqueline Emery, BSEE, Principal
Cliniquest, Inc.
74 Pleasant St.
Westford, MA 01886

Re: K072049
Trade Name: NEXFIN_HD Continuous Non-Invasive Hemodynamic Monitor
Regulation Number: 21 CFR 870.1130
Regulation Name: Non-invasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Codes: DXN, DSB
Date: November 20, 2007
Received: November 21, 2007

Dear Ms. Emery:

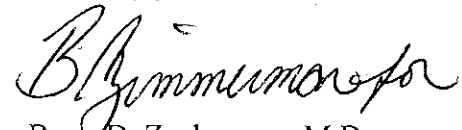
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Brain D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): ___K072049 _____

Device Name: ___NEXFIN_HD Non-Invasive Hemodynamic Monitor_____

Indications for Use:

The BMEYE NEXFIN_HD is intended to, non-invasively and continuously, measure blood pressure and hemodynamic parameters in adult patients. The NEXFIN_HD monitor should be calibrated with a thermodilution measurement, or other accurate reference determination of cardiac output, to ensure optimal accuracy. The device is intended for use by physicians or other properly trained medical personnel in a hospital or other appropriate clinical setting.

William Bednarski

William Bednarski
Chief Executive Officer
BMEYE B.V.

OCTOBER 4, 2007
Date

Prescription Use _____✓_____ AND/OR Over-The-Counter Use _____
Part 21CFR 801 Subpart D) (21CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE _ CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

B Symmums

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K072049